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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/060,409	04/14/1998	DINAH W. Y. SAH	860098.420	9564

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EXAMINER

FALK, ANNE MARIE

ART UNIT	PAPER NUMBER
1632	39

DATE MAILED: 08/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/060,409	SAH ET AL.
	Examiner	Art Unit
	Anne-Marie Falk, Ph.D.	1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 20 May 2003.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 6-16 and 47-78 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 6-16, 47, 48, 53, 62-65, 75, and 76 is/are allowed.
- 6) Claim(s) 49-52, 54-61, 66-74, 77 and 78 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 14 April 1998 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

Art Unit: 1632

### **DETAILED ACTION**

The amendment filed May 20, 2003 (Paper No. 38) has been entered. Claims 50, 51, 60-63, 66-69, 74, 75, 77, and 78 have been amended.

Accordingly, Claims 6-16 and 47-78 are pending in the instant application.

The following rejections are reiterated or newly applied and constitute the complete set of rejections being applied to the instant application. Rejections and objections not reiterated from the previous office action are hereby withdrawn.

#### *Drawings*

The draftsperson has objected to the drawings. See the PTO-948 attached to the Office Action of Paper No. 11 (mailed 10/6/00). Applicant is required to submit the drawing corrections within the time period set for response to this Office Action. Applicant may not request that any objection to the drawings be held in abeyance. See 37 CFR 1.85(a). Failure to take corrective action within the set period will result in ABANDONMENT of this application.

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 49, 52, 54-59, and 70-73 stand rejected under 35 U.S.C. 112, first paragraph, for reasons of record advanced on pages 2-4 of the Office Action of Paper No. 19 (mailed 6/5/01) and on pages 2-4 of the Office Action of Paper No. 34 (mailed 11/19/02), as containing subject matter which was not

Art Unit: 1632

described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 49 and 52 are directed to neurons produced from conditionally-immortalized dorsal root ganglion progenitor cells.

Claims 54-59 and 70-73 are directed to methods for transplanting cells into a mammal or patient.

At pages 12-13 of the response, Applicants argue that the enablement rejection set forth in Paper No. 19 is not applicable to the neurons claimed in Claims 49 and 52. However, the specification teaches that the only use for the neurons of the invention is for therapeutic transplantation. Thus, the same grounds of rejection set forth with regard to the methods of transplantation are applicable to the compositions as well because the specification must provide an enabling disclosure teaching how to use the claimed compositions.

At page 13, paragraph 4 of the response, Applicants argue that the Jackowski reference is directed to the failure of CNS, not PNS neural regeneration. This is not the case. The reference explicitly refers to membrane- or extracellular matrix-associated molecules that inhibit the successful regeneration of adult mammalian CNS and PNS axons (see page 311, column 1, paragraph 2).

At page 13, paragraph 5 of the response, Applicants argue that, in addition to therapeutic transplantation, the claimed transplantation methods can be used in “transplantation studies” and that “[t]hese studies encompass research on the transplanted cells themselves, as part of basic research, and are not limited to research solely directed to therapeutic regimens.” However, research is not considered a substantial utility. The Utility Guidelines Training Materials specifically state that a substantial utility defines a “real world” use and that basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved do not define substantial utilities, but rather constitute carrying out further research to identify or reasonably confirm a “real world” context of use.

See the Utility Guidelines at [www.uspto.gov/web/menu/utility.pdf](http://www.uspto.gov/web/menu/utility.pdf) particularly page 6 which discusses the

Art Unit: 1632

requirements for a substantial utility. Furthermore, it is well established that the specification must enable the full scope of the claims and the claims clearly cover therapeutic transplantation.

The rejections of Claims 12-16, 60-69, and 74-78 under 35 U.S.C. 112, first paragraph are withdrawn in view of the claim amendments and Applicants' arguments.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 60, 61, 66-69, 74, 77, and 78 stand rejected and Claims 50-52 are rejected under 35 U.S.C. 112, second paragraph, for reasons of record advanced on pages 5-7 of the Office Action of Paper No. 19 (mailed 6/5/01) and on pages 4-5 of the Office Action of Paper No. 34 (mailed 11/19/02), as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 50-52 are indefinite in their recitation of the first instance of "the oncogene" in line 2 of Claim 50 because the term lacks antecedent basis.

Claims 60, 61, and 74 are indefinite in their recitation of "comparing the level or activity of said protein in the presence of said agent with the level or activity of said protein in the absence of said agent" because no measurements have been taken to determine the level or activity of any protein in either the presence or absence of the candidate agent.

Claim 66 is indefinite in its recitation of "said plurality of cells" because the phrase lacks antecedent basis.

Claims 66, 67, and 77 are indefinite in their recitation of "subsequently comparing the number of said plurality of cells that die in the presence of said agent to the number of said plurality of cells that die in the absence of said agent" because no measurements have been taken to determine the number of cells that die in either the presence or absence of the agent.

Art Unit: 1632

Claims 68, 69, and 78 are indefinite in their recitation of "comparing the number of said plurality of cells that die when said level of expression is altered to the number of said plurality of cells that die when said level of expression is not altered" because no measurements have been taken to determine the number of cells that die when the level of expression of a protein is either altered or not altered.

*Conclusion*

Claims 6-16, 47, 48, 53, 62-65, 75, and 76 are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (703) 306-9155. The examiner can normally be reached Monday through Thursday and alternate Fridays from 10:00 AM to 7:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, William Phillips, whose telephone number is (703) 305-3482.

Anne-Marie Falk, Ph.D.

*Anne-Marie Falk*  
ANNE-MARIE FALK, PH.D.  
PRIMARY EXAMINER